

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TALECRIS BIOTHERAPEUTICS, INC., and)
BAYER HEALTHCARE LLC,)

Plaintiffs,)

v.)

BAXTER INTERNATIONAL INC., and)
BAXTER HEALTHCARE CORPORATION,)

Defendants.)

C.A. No. 05-349-GMS

Jury Trial Demanded

BAXTER HEALTHCARE CORPORATION,)

Counterclaimant,)

v.)

TALECRIS BIOTHERAPEUTICS, INC., and)
BAYER HEALTHCARE LLC,)

Counterdefendants.)

REDACTED VERSION DI 310

**PLAINTIFFS' REPLY BRIEF IN SUPPORT OF THEIR MOTION *IN LIMINE* NO. 5
TO PRECLUDE CERTAIN EXPERT TESTIMONY OF THOMAS J. KINDT, Ph.D.**

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Redacted Version Filed: May 21, 2007
Date: May 14, 2007

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Plaintiffs hereby reply to Baxter's opposition to Plaintiffs' motion *in limine* to prohibit Baxter's expert, Dr. Thomas J. Kindt from providing any opinions relating to inherency as it relates to Baxter's anticipation and obviousness defenses, and to prevent Dr. Kindt from relying on any combination of references that is not listed on TAL246 or 262.

1. DR. KINDT'S OPINIONS ON INHERENCY SHOULD BE EXCLUDED

Baxter argues that despite the fact that Dr. Kindt does not agree that all solvent/detergent steps inherently elevate ACA (Mason Dec.¹ Ex. 8, 151:20-152:3), the Court should allow him to testify that all conditions do, *in fact*, elevate ACA based on Plaintiffs' alleged admissions. Such a position is scientifically, factually, and legally incorrect. Baxter's argument ignores the scientific testimony of their own expert and the inventor.

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Since the scientific facts do not fit Baxter's argument, they attempt to rely on statements made during prosecution which were directed to the data before the PTO and not the body of art involving S/D process steps. Plaintiffs do not, and have never, asserted that all S/D treatment conditions inherently elevate ACA, but have merely stated that all the conditions tested under controlled conditions by Dr. Alonso have shown an elevation of ACA. Baxter's position distorts the documents and factual record. The quotes relied upon by Baxter clearly relate to the solvent/detergent conditions disclosed in the patent specification that were tested by Dr. Alonso. Whether an S/D condition inherently elevates ACA *is an empirical inquiry*.

Baxter also argues that somehow the patentee's statements can form the basis for a finding of inherency. This demonstrates a basic lack of understanding of the legal standards for

¹ The "Mason Dec." is the Declaration of Jaelyn M. Mason in Support of Plaintiffs' Reply Briefs in Support of Their Motions *in Limine* Nos. 1-5, filed concurrently herewith.

inherency. Inherency is an issue of fact that requires a showing that the claim element is necessarily contained in the prior art reference such that one skilled in the art would recognize such a disclosure. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) (“the question whether a claim limitation is inherent in a prior art reference is a factual issue on which evidence may be introduced”); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154 (Fed. Cir. 1998) (to prove inherency the missing claim element must necessarily be present in the prior art reference such that one skilled in the art would recognize such a disclosure). Plaintiffs’ statements cannot relieve Baxter of its burden to prove inherency.

REDACTED

2. THE COURT SHOULD EXCLUDE ALL OPINIONS ON OBVIOUSNESS BECAUSE OF DR. KINDT’S RELIANCE ON HINDSIGHT

Baxter again demonstrates its propensity to weave together unrelated threads of out-of-context quotes to support their strained positions. The quotes from Dr. Kindt’s deposition relied upon by Baxter are not related to the methods actually utilized by Dr. Kindt to form his obviousness opinions.

REDACTED

As discussed in Plaintiffs’ opening motion, his answer clearly demonstrates the use of hindsight. Dr. Kindt’s analysis is completely improper,

and must be excluded. Moreover, Plaintiffs' analysis is completely consistent with the Supreme Court's recent ruling in *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (1997).

3. DR. KINDT SHOULD BE PRECLUDED FROM RELYING ON ANY PRIOR ART COMBINATIONS THAT ARE NOT LISTED ON EXHIBITS TAL 246 OR 262.

Baxter asserts that Dr. Kindt disclosed all the prior art combinations upon which he relied in his expert report. In fact, Dr. Kindt provided the following statement in his expert report:

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(Mason Dec., Ex. 10 at 20.) This "sentence" can only be construed in one of two ways. Either Dr. Kindt opined that all 14 references must be combined to render the claims of the '191 patent obvious, or there are various combinations within this set of references that would result in a finding of obviousness. Plaintiffs were unable to determine Dr. Kindt's meaning from this passage. As a result, Dr. Kindt was asked to list the prior art combinations upon which he would be relying. He was given an unlimited amount of time and had access to his expert report and any other reference that he required. (*Id.*, Ex. 8 at 204:18-205:1, 244:13-245:7.) Dr. Kindt should not be allowed to rely on a long recitation of various references, without clearly identifying those upon which he will rely. To allow this would be to deny Plaintiffs the ability to respond to each combination at trial, which would be unduly prejudicial. As such, Dr. Kindt's testimony should be limited to the combinations listed on TAL 246 and 252.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify on this 14th day of May, 2007 I electronically filed the foregoing **Plaintiffs' Reply Brief in Support of Their Motion *in Limine* No. 5 to Preclude Certain Expert Testimony of Thomas J. Kindt, Ph.D.** with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

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I also hereby certify that a true copy of the foregoing document was served upon the following in the manner indicated on May 14, 2007.

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